# Regulatory Essentials – November 20, 2019

## Cosmetics Alliance Updates

Register for the Fall Regulatory Workshop!

Date: December 12th 2019

Hear from government officials and Cosmetics Alliance staff on issues that will directly affect your business.

Important topics that will be covered:

- Sunscreen Pilot & Expansion
- NHPID Process
- Hotlist Updates / Process
- Updates to PLL, Compliance & Enforcement Approach
- Self Care Framework Updates from Summer & Fall
- Upcoming changes to Cost Recovery program for cosmetic-like drugs
- How Health Canada's Food and Drug Act Liaison Office can assist in facilitating conversations with officials

Register

Cosmetics 101

Introduction to Cosmetics in Canada

December 3, 2019

2:00 - 3:30 plus 1/2 h quiz

Designed for New · Employees · New Cosmetics Alliance Members · Refresher Course

Objectives

- Learn the language of cosmetics in Canada
- Understand the set-up of Canadian Law
- Overview of the Cosmetic Regulations
- Enable attendees to access the Canadian market
- Health Updates

Register

Cosmetic Labelling 101 Introduction to Cosmetic Labelling for Canada

December 19, 2019

2:00 - 3:30 pm plus1/2 h quiz

Designed for New Employees and New Cosmetics Alliance Members

Objectives

- Lean the language of cosmetics in Canada
- Overview of the Cosmetic Labelling Regulations
- Learn how other Canadian regulations apply to cosmetics
- Understand how these regulations interact with each other

Register

**Only those electronically registered will be able to take the quiz and receive a training certificate. Limited spaces available!**

Health Canada Hosting Training Sessions on Cost Recovery Fees

The *Fees in Respect of Drugs and Medical Devices Order* (https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-124/FullText.html) were published in May 2019, and will come into force on April 1, 2020. Health Canada will be hosting training sessions via WebEx on November 26-28 to walk stakeholders through the revised Guidance documents.

The sessions relevant to our industry are as follows (including registration links):

*Drugs (Human, Disinfectant and Over-the-Counter) (Evaluation and Right to Sell Fees)*

November 28 - 10:00 a.m. to 12:00 p.m. (EST)

https://www.eventbrite.ca/e/cost-recovery-training-formation-sur-le-recouvrement-des-couts-tickets-78078654357

*Drugs (Human and Veterinary) (Establishment Licence Fees)*

November 28 - 1:00 p.m. to 3:00 p.m. (EST)

https://www.eventbrite.ca/e/cost-recovery-training-formation-sur-le-recouvrement-des-couts-tickets-78071362547

There will also be sessions for Medical Devices and Veterinary Health Products. Cosmetics Alliance will be taking part in both human drug sessions

Pre-market guidance documents are available on Health Canada's website at https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees.html. Post-market establishment licensing guidance documents will be emailed directly to Establishment License holders and will subsequently be posted on Health Canada's website.

Drug Facts Labelling for Off-Monograph Products

Cosmetics Alliance has been having ongoing conversations with the NNHPD regarding transitional considerations for existing "off-monograph" products to come into compliance with Plain Language Labelling (PLL) requirements, specifically the Canadian Drug Facts Table (CDFT), by the June 2021 deadline. As a reminder, the *Guidance Document: Labelling Requirements for Non-prescription Drugs* (https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/labelling-requirements-non-prescription-drugs.html) provides for the following Flexibilities for low-risk cosmetic-like drugs:

- Section 2.5: Tailored Flexibilities for Category IV Products, Mouthwashes and Toothpastes (which provides for opportunities to optionally pursue an electronic labelling extension to facilitate compliance); and
- Section 2.6: Labelling for Low Risk Non-Prescription Drugs (i.e. SCF Category 1 Products):

> "Effective December 2018, select Category IV products, mouthwashes, and toothpastes that are considered to be low risk and that align with the applicable monograph, will be considered as Category I products under the Self Care Framework. These products will not be required to present the labelling information in tabular format and will have access to the flexibilities listed in Table 5.
>
> Only those products that fully align with the following monographs or combinations thereof (to be updated by December 2018) will be subject to the flexibilities described in Table 5:
>
> - Acne Therapy
> - Anti-Dandruff Products
> - Antiseptic Skin Cleansers (Domestic/Personal Care Use)
> - Diaper Rash Products
> - Oral Health
> - Medicated Skin Care Products
> - Sunscreen
>
> Any other Category IV products that do not fully align with the above listed monographs or combinations thereof will not have access to the Category I flexibilities presented in Table 5, nor the Category IV products, mouthwashes, and toothpastes flexibilities presented in Table 4, as of December 1st, 2018."

As noted above, PLL flexibilities afforded to Category I self-care products are only available to products that fully align with the relevant monograph. This means that products that have applied "off-monograph" cannot avail themselves of these flexibilities.

Based on discussions related to the SCF, it is our understanding that once the Framework is in place, products will be categorized according to their risk and treated in a "like-for-like" manner and products that are currently considered "off-monograph" will in fact be categorized in the lowest risk category (Category 1 SCF) alongside monographed products. Therefore, "off-monograph" products that will require full CDFT labelling by 2021 (by virtue of the present guidance) will ultimately be considered to be 'pre-cleared', effectively providing for optional inclusion of CDFTs. The result is that companies with "off monograph" products are being forced to revise their labels to include full CDFT labelling in order to come into compliance with the PLL regulations by 2021. Whereas these labelling requirements would become optional under the SCF, thus companies find themselves in the position of having to change labels twice – in the absence of an interim solution to address these potential duplicative efforts.

Our ongoing conversations with NNHPD have been constructive and we believe they recognize the desire to avoid duplicative labelling for these existing "off-monograph" products. They have

asked us to provide them with some specific information so that they can better understand the scope of this problem for our members. If your company has “off-monograph” products in its portfolio, **please contact us by no later than Friday, November 22.**

Updates to Cosmetic Notification Form Ingredient Validation Text for Sodium Perborate

As indicated on the Hotlist, Sodium perborate is captured under the entries for both **Peroxide and peroxide-generating compounds** and **Boric acid and its salts**. However, Health Canada has recently noticed that the condition text provided in cosmetic notification form (ingredient validation) only mentioned the Peroxide entry. They have therefore revised the text for the following ingredient names to provide the conditions for both applicable entries to sodium perborate:

Perborate de sodium

PERBORIC ACID, SODIUM SALT

SODIUM PERBORATE

SODIUM PERBORATE MONOHYDRATE

SODIUM PEROXOBORATE

## Post-Consumer Waste Updates

Ontario Government Webinar on Blue Box Transition – Register Now

The Government of Ontario is moving forward with the next steps in transitioning the Blue Box program to full producer responsibility. The Ontario Ministry of the Environment, Conservation and Parks will hold a webinar on **November 27, 2019.** The webinar will explain how you can take part in the development of a new regulation that will define how the producer-run Blue Box system will work. If you are interested in participating, please register by November 22, 2019 with Marc Peverini, Senior Policy Analyst, Resource Recovery Policy Branch at Marc.Peverini@ontario.ca or 416-908-1528.

Transitioning the Blue Box program to producer responsibility will be a multi-stage process that will involve many opportunities for input. As previously communicated, on August 15, 2019, Minister Yurek took the first step in transitioning the Blue Box program to full producer responsibility by directing Stewardship Ontario to develop a plan outlining how the existing municipally-run program will continue until producers take over full operation between 2023 and 2025. The next stage is the development of a regulation under the Resource Recovery and Circular Economy Act as well as any regulatory amendments necessary to end municipalities’ obligation to provide Blue Box services.

Input from all stakeholders is being sought. As well, the ministry has established three working groups representing producers, municipalities and waste management and packaging manufacturers. A policy paper is to be released in spring 2020 for public consultation. It will outline the key elements and proposed approach for a new producer responsibility regulation. This will include maintaining a convenient and accessible collection system,

identifying a standardized list of materials to be collected (including considering how best to deal with single use plastics), and setting targets or other performance targets. A draft regulation will be prepared and consulted on later in the year. The goal is to finalize the regulation early in 2021.

Ontario proposes changes to RPRA mandate

The Ontario Ministry of the Environment, Conservation and Parks is proposing to change the mandate of the Resource Productivity and Recovery Authority (RPRA, the Authority) to include digital reporting services through its registry for a wider range of waste and resource recovery programs. It is proposed that combining digital services would save businesses time and money as there would be a larger group of users sharing common program costs and benefiting from the Authority's modern registry.

The proposed change in mandate for the Authority will require an amendment to the Resource Recovery and Circular Economy Act, the Environmental Protection Act and the Waste Diversion Transition Act. At this time, the ministry is proposing to transition the reporting service for Ontario's Hazardous Waste Information Network (HWIN), which it currently operates to track industrial hazardous or liquid waste. Costs of the program are proposed to be recovered from users of HWIN. By moving towards a modern digital service, it is proposed that Ontario would be eliminating the administrative burden of processing over 450,000 paper documents for the HWIN program.

The ministry has posted these proposed changes to the Environmental Registry https://ero.ontario.ca/notice/019-0671 and the Regulatory Registry for a 30 day comment period from October 28, 2019 until **November 27, 2019**.